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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,436	10/22/2003	Sharon Mi Lyn Tan	12712/46001	3696

23838 7590 02/09/2006

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EXAMINER

THANH, LOAN H

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 02/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/690,436

Applicant(s)

TAN, SHARON MI LYN

Examiner

LoAn H. Thanh

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>09/06/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Except for the prior art label of figure 1 , the drawing objections are maintained.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the region of catheter comprising a material which permits passage of an antimicrobial agent release from the intervention device from the catheter lumen to an outer surface of the catheter (cls. 6 & 15), the cap is a stopper (cls. 9 & 18) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

The drawings are objected to because the threaded portion of the cap and sidearm is not shown or labeled with a reference numeral (cls. 8 & 17).

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for

consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liu et al. (USPN 6,371,944) in view of Davidson (USPN 5,588,443).

Liu et al. disclose a system for use in the body comprising a catheter 7, a side arm, a lumen through the side arm 9, which communicates with the catheter lumen and a one-way valve 5 and an intervention device such as the wire 18. Liu et al. however does not teach the wire to be coated with an antimicrobial agent. Davidson discloses a wire for use in the body, which is coated with antimicrobial, anticoagulants or, medicaments as desirable or for reducing adhesion or other adverse cellular or tissue response to surfaces in contact with blood. See column 4, lines 25-35. It would have been obvious to one of ordinary skill in the catheter art at the time the invention was

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made to modify the wire used to contact with blood of Liu et al. with an antimicrobial coating as taught by Davidson in order to prevent infections within the internal system of the patient.

With respect to claims 5 and 14, it is well known in the surgical and medical arts to prepare/swab a patient with iodine before injecting or surgically introducing a device into a patient. With that knowledge in mind, it would have been obvious to one of ordinary skill to swab/coat a device with Iodine as a mere obvious selection of medicament which would prevent infection.

With respect to claims 7-9 and 16-18, Liu et al does not disclose a threaded or stopper cap with the rod affixed to the cap. Fischell et al. disclose a sealing cap 80 for sealing the system to reduce the blood loss when inserting guiding catheters/rods/wires. See figures 1-3 which discloses a stopper cap and figure 7 which disclose a threaded cap. It would have been obvious to one of ordinary skill in the medical art to modify the device of Liu et al. with an end cap for the side arm as taught by Fischell et al. in order to reduce blood loss when inserting the wire into the side arm.

With respect to the claims 20-26, the intervention device is capable of performing the function of remaining in the catheter lumen during fluid flow. Further, it is also considered to be associated with a hemodialysis procedure lacking any structural distinguishing features. Injections and infusions are well known procedures which are associated with hemodialysis.

Response to Arguments

Applicant's arguments filed 11/21/05 have been fully considered but they are not persuasive. Applicant argues on page last paragraph of the remarks filed 11/21/05 that "nothing in Davidson suggest the release of the wire coating from the guide wire". The Examiner is not agreement. It is an inherent property of medical coating of therapeutic agents to diffuse into the blood stream or body fluids. Applicant is invited to see column 4, lines 32-35. Davidson teaches the coating would be "as needed for the particular application". Davidson does not teach away from the separation of the coating since

Davidson teaches that the thickness of the coating is frequently not critical but in the limited circumstances that applicant has cited . It is maintained that Davidson teaches a coating regardless and that it is an inherent property and an inherent function that the coating (antibiotic or anticoagulant) will diffuse or be configured to be released from the guidewire.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LoAn H. Thanh whose telephone number is (571) 272-4966. The examiner can normally be reached on Mon. - Fri. (First Friday off).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'LoAn H. Thanh', with a stylized flourish at the end.

LoAn H. Thanh
Primary Examiner
Art Unit 3763

LT
02/06/06